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PROPENSITY-MATCHED PATIENT LEVEL COMPARISON OF THE TAXUS LIBERTÉ AND TAXUS ELEMENT (ION) PACLITAXEL-ELUTING STENTS: DOES STENT PLATFORM MAKE A DIFFERENCE?

i2 Poster Contributions
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Background: The TAXUS Element paclitaxel-eluting stent (PES) uses the same polymer and drug as the prior-generation TAXUS Express and TAXUS Liberté PES, but with a novel platinum chromium metal alloy and a thin 81µM strut design. In the PERSEUS trial, 12-month outcomes were comparable for TAXUS Element and TAXUS Express; however, no comparison has yet been made to the more contemporary TAXUS Liberté PES.

Methods: Patient-level data from 2298 subjects treated with PES were pooled from the TAXUS ATLAS (TAXUS Liberté Stent) and PERSEUS (TAXUS Element Stent) trials and 1:1 propensity-matched to adjust for significant baseline differences.*

Results: MACE, TLF, MI, and non-Q-wave MI were significantly lower in the TAXUS Element versus the TAXUS Liberté group, with and without propensity matching (see Table). TVR and TLR were significantly lower with TAXUS Element in the unadjusted analysis, but differences were not significant following propensity matching. Concordant results were seen in subjects treated with single stents only (not shown in Table; to be presented).

Conclusion: In this exploratory post hoc analysis, TAXUS Element was associated with fewer clinical events than TAXUS Liberté, largely driven by reduced peri-procedural non-Q-wave MI. These differences may be explained by thinner struts and modified cell design in the TAXUS Element stent, although evolution in adjunctive therapies and stenting technique may also be contributory.

Unadjusted	TAXUS Liberté (N=1132)	TAXUS Element (ION)† (N=1166)	P Value
MACE	12.7% (143)	8.3% (95)	<0.001
Cardiac Death	0.9% (10)	0.7% (8)	0.60
Myocardial Infarction	3.6% (41)	1.9% (22)	0.01
- Q-Wave	0.7% (8)	0.5% (6)	0.56
- Non-Q-Wave‡	2.9% (33)	1.4% (16)	0.01
--- In-Hospital NQWMI	2.1% (24)	1.3% (15)	0.12
TVR	9.6% (107)	6.8% (77)	0.02
TLR	6.2% (69)	4.2% (48)	0.04
TLF	9.0% (101)	5.9% (68)	0.006
All Death	1.6% (18)	0.8% (9)	0.08
Stent Thrombosis§	1.0% (11)	0.4% (5)	0.13
Late Loss, In-Stent	0.37±0.52 (653)	0.36±0.53 (425)	0.73
Binary Restenosis, Segment	15.6% (103/660)	11.1% (47/425)	0.03
1:1 Propensity Matched	TAXUS Liberté (N=663)	TAXUS Element (ION)† (N=663)	P Value
MACE	12.0% (79)	7.5% (49)	0.007
Cardiac Death	0.8% (5)	0.8% (5)	0.99
Myocardial Infarction	3.9% (26)	1.8% (12)	0.02
- Q-Wave	0.8% (5)	0.9% (6)	0.76
- Non-Q-Wave‡	3.2% (21)	0.9% (6)	0.004
--- In-Hospital NQWMI	2.4% (16)	0.8% (5)	0.02
TVR	8.8% (58)	6.5% (42)	0.12
TLR	5.7% (37)	4.2% (27)	0.23
TLF	8.5% (56)	5.5% (36)	0.04
All Death	1.2% (8)	0.8% (5)	0.41
Stent Thrombosis§	0.9% (6)	0.5% (3)	0.32
Late Loss, In-Stent	0.42±0.56 (322)	0.33±0.53 (336)	0.04
Binary Restenosis, Segment	14.9% (48/322)	9.8% (33/336)	0.047

*Significant unadjusted baseline differences in TAXUS Element group relative to TAXUS Liberté group: larger RVD, shorter lesion length, smaller MLD, larger %DS, fewer AHA/ACC B2/C lesions. TAXUS Element also had greater maximum deployment pressure and smaller stented length. Percent multiple and overlapping stents and average number of study stents implanted were comparable between groups.
†TAXUS Element will be commercialized under the name ION Stent in the United States.
‡De novo elevation of CK Total levels >2.0 x ULN without the presence of new Q-waves. If CK-MB was performed, it must have been positive.
§Academic Research Consortium Definite/Probable
Clinical data are presented as % (number of events) and are based on Kaplan-Meier estimates with a log-rank P value. Late Loss presented as mean±standard deviation.
Abbreviations: MACE: major adverse cardiac events (cardiac death, MI, target vessel revascularization); MI: myocardial infarction; NQWMI: non-Q-wave MI; RVD: reference vessel diameter; TLF: target lesion failure (TLR, target-vessel-related MI, target-vessel-related cardiac death); TLR: target lesion revascularization; TVR: target vessel revascularization.